

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

1201 NORTH MARKET STREET

P.O. Box 1347

WILMINGTON, DELAWARE 19899-1347

302 658 9200

302 658 3989 FAX

JACK B. BLUMENFELD

302 351 9291

302 425 3012 FAX

jblumenfeld@mnat.com

January 26, 2006

The Honorable Kent A. Jordan
United States District Court
844 North King Street
Wilmington, DE 19801

Re: Biovail v. Andrx Pharmaceuticals LLC et al.,
Civil Action No. 05-586 (KAJ)

Dear Judge Jordan:

Plaintiff Biovail hereby responds to Defendant Andrx's January 25, 2006 letter ("Andrx letter") requesting the Court to compel Biovail to supplement its interrogatory responses and produce additional documents.

I. Background Of The Dispute

This is the second litigation involving Biovail, Andrx, and the patent-in-suit, U.S. Patent No. 5,529,791 (the "791 patent"). In the first litigation, Biovail produced and made available for inspection nearly 30,000 pages of documents. In this litigation, Biovail produced an additional 18,317 pages of documents, many of which were produced, in the spirit of cooperation, following complaints received from Andrx.

On January 3, 2006, Andrx complained that Biovail's production was "anemic." In response, Biovail asked Andrx to identify specifically "what additional documents Andrx seeks." Rather than meeting and conferring, or even responding to this request, Andrx submitted its omnibus letter seeking to compel production on 60 document requests. (See Andrx's January 3, 2006 and Biovail's January 11, 2006 letters, Exhs. A and B, respectively.)

In the first litigation, the only issue litigated through appeal was infringement. In this litigation, Andrx has asserted a boilerplate obviousness defense. As the Court knows, the defense of obviousness entails the following factors: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; and (3) the differences between the claimed invention and the prior art. *Robotic Vision Sys., Inc. v. View Eng'g, Inc.*, 189 F.3d 1370, 1376 (Fed. Cir. 1999). If a defendant makes a *prima facie* case of obviousness, then a

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plaintiff **may** rebut that showing with secondary considerations of nonobviousness, including long-felt need, commercial success, failure of others, copying, and unexpected results. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 291-292 (Fed. Cir. 1985), *cert denied*, 475 U.S. 1017 (1986). In interrogatories, Biovail asked Andrx to explain its boilerplate allegations of obviousness. In response, Andrx stated only that “if the claims of the ’791 patent are interpreted to include the Andrx Proposed Product, then the claims are invalid under 35 U.S.C. § 102(b) and/or 103(a) in view of the teachings of EPO 0 320 097” (See Exh. C.) Although there is a passing reference to § 103 (obviousness), Andrx has made no effort to articulate this defense, including an explanation of the claims that it asserts are invalid, and why those claims are invalid pursuant to each of the factors identified above. Biovail has asked Andrx again to explain its obviousness contentions, but so far Andrx has not done so. (See Biovail’s January 24, 2006 letter, Exh. D.)

II. Andrx’s Complaints Regarding Biovail’s Interrogatory Responses Are Unfounded

In response to Andrx’s complaints, Biovail sent Andrx a letter explaining its position regarding interrogatory responses, and agreeing to supplement its responses to Interrogatories Nos. 1 and 4. (See Exh. A.) Andrx never responded to Biovail’s letter, much less met and conferred regarding Biovail’s supplemental responses.

Interrogatory Nos. 1 and 4 seek Biovail contentions regarding infringement. Biovail’s supplemental responses reflect the current state of its infringement contentions. If further factual support or contentions are developed during fact discovery, in accordance with its obligations under Federal Civil Procedure Rule 26(e), Biovail will further supplement its responses at that time. Notably, Biovail is currently working with its experts to explore and develop their opinions regarding infringement. According to the current discovery schedule, these expert reports are due on May 16, 2006.

Interrogatory Nos. 2-3 seek information regarding the dates of conception, reduction to practice, and first synthesis of the inventions of the ’791 patent. The inventions of the ’791 patent were conceived, reduced to practice, and first synthesized by third-parties, inventors Arthur Deboeck and Philippe Baudier, who are not under Biovail’s control. Andrx has subpoenaed documents and testimony from inventor Arthur Deboeck, through which Andrx may seek the information it requested. However, Andrx has not made clear why any of the dates it seeks are relevant, and Biovail has no further responsive information in its custody and control at this time.

Interrogatory Nos. 6-7 seek information regarding secondary considerations, and the first sale and use of Biovail’s Cardizem® LA products. As explained above, Andrx has yet to support any invalidity contention that would invoke the need to provide the requested information.

Interrogatory No. 8 seeks technical information regarding the manufacture of Biovail’s Cardizem® LA products. Pursuant to Federal Civil Procedure Rule 33(d), Biovail identified a discrete section of its New Drug Application (“NDA”) from which the answer

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may be derived or ascertained. (*See* Exh. A.) Indeed, the description of Biovail's process for manufacturing Cardizem® LA comprises less than 15 pages, and is easily identified from the table of contents of Biovail's NDA.

Interrogatory No. 9 seeks the identity of persons who provided information included, or considered for inclusion, in Biovail's responses to Andrx's interrogatories and document requests. Andrx never raised a complaint regarding Biovail's response to this interrogatory, and thus has not even attempted to satisfy its meet and confer obligation.

III. Andrx's Complaints Regarding Biovail's Document Production Likewise Lack Merit

As explained above, Andrx has never specifically articulated, in correspondence, or to this Court, precisely what documents Biovail allegedly has not produced. It is woefully inadequate to ask this Court to compel on 60 document requests based solely on the casual assertion that "it would be surprising if more [documents] were not available and readily accessible." (*See* Andrx letter, footnote 1.)

Consistent with its Objections to Andrx's document requests, and as discussed above, Biovail has not produced documents that are only relevant to secondary considerations of nonobviousness, such as marketing, sales and financial information, on the grounds that Andrx has not articulated any, let alone a *prima facie*, case of obviousness. Biovail should not be required to produce highly sensitive commercial and financial information in the absence of any *prima facie* defense of obviousness. Beyond those types of documents, Biovail is not withholding any relevant, non-privileged, non-work product documents that are responsive to Andrx's requests.

Finally, as to Andrx's suggestion that Biovail has failed to produce documents from the earlier litigation that Andrx claims it no longer has, Biovail told Andrx that it would do so, but also wanted Andrx to agree to produce documents that Biovail no longer has from the first litigation. Although Andrx said that it would search for the documents Biovail requested, Biovail has not received any further response. Biovail stands ready to exchange documents from the earlier litigation pursuant to the parties' agreement.

Respectfully,



Jack B. Blumenfeld (#1014)

JBB/dam

cc: Peter T. Dalleo, Clerk (By Hand)
 William J. Cattie, III, Esquire (By Hand and E-Mail)
 Steven A. Maddox, Esquire (By E-Mail)
 Matthew C. Marlowe (By E-Mail)
 Joseph M. O'Malley, Jr., Esquire (By E-Mail)